IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

OREXO AB and OREXO US, INC.,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	C.A. No. ____________________________
	)	
ACTAVIS ELIZABETH LLC, ACTAVIS PHARMA, INC., TEVA PHARMACEUTICALS USA, INC., and TEVA PHARMACEUTICAL INDUSTRIES, LTD.	)	JURY TRIAL DEMANDED
	)	
Defendants.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Orexo AB ("Orexo AB") and Orexo US, Inc. ("Orexo US") (collectively, "Plaintiffs"), for their Complaint against defendants Actavis Elizabeth LLC ("Actavis Elizabeth"), Actavis Pharma, Inc. ("Actavis Pharma"), Teva Pharmaceuticals USA, Inc. ("Teva USA"), and Teva Pharmaceutical Industries, Ltd. ("Teva Ltd.") (collectively "Defendants"), hereby allege as follows:

OVERVIEW OF THE ACTION

1. This is a patent infringement action pursuant to 35 U.S.C. § 271(b)&(c) arising from Defendants' infringement of Orexo's United States Patent No. 8,454,996 ("the '996 patent") via the manufacture, use, sale, offer to sell, importation, and instructions for use to physicians and patients of Actavis Elizabeth's generic versions of Suboxone® buprenorphine and naloxone products (ANDA No. 091422) and Actavis Elizabeth's generic versions of Subutex® buprenorphine products (ANDA No. 090819).

2. Actavis Elizabeth's generic versions of Suboxone® products at issue in this litigation include two dosage strengths, the 2mg/0.5mg and 8mg/2mg tablets (referring to the

amount of buprenorphine/naloxone active ingredients in each tablet). These products are referred to herein as "generic Suboxone® products." Actavis Elizabeth's generic versions of Subutex® buprenorphine products at issue in this litigation also include two dosage strengths, 2mg and 8mg tablets. These products are referred to herein as "generic Subutex® products."

THE PARTIES

3. Plaintiff Orexo AB is a company organized and existing under the laws of Sweden, having its principal place of business at Virdings allé 32 A, 754 50 Uppsala, Sweden.

4. Plaintiff Orexo US is a corporation organized and existing under the laws of the state of Delaware, having its principal place of business at 150 Headquarters Plaza, East Tower, Morristown, New Jersey 07960. Orexo US is a wholly owned subsidiary of Orexo AB.

5. Defendant Actavis Elizabeth is a company organized and existing under the laws of the state of Delaware, having a principal place of business at 200 Elmora Avenue, Elizabeth, New Jersey 07202. Actavis Elizabeth manufactures generic drugs, including the generic Suboxone® products and generic Subutex® products, for sale and use throughout the United States, including in this District and including as a subsidiary and agent of Teva USA and Teva Ltd.

6. Defendant Actavis Pharma, Inc. is a corporation organized and existing under the laws of the state of Delaware, having a principal place of business at 400 Interpace Parkway, Parsippany, New Jersey 07054. Actavis Pharma distributes generic drugs, including the generic Suboxone® products and generic Subutex® products, for sale and use throughout the United States, including in this District and including as a subsidiary and agent of Teva USA and Teva Ltd.

7. Teva Pharmaceuticals USA, Inc. is a corporation organized and existing under the laws of the state of Delaware, having a principal place of business at 425 Privet Road,

Horsham, Pennsylvania 19044. Teva USA develops, manufactures, sells and/or distributes generic drugs, including the generic Suboxone® products and generic Subutex® products throughout the United States, including in this District and including through its subsidiaries and agents, Actavis Elizabeth and Actavis Pharma.

8. Teva Pharmaceutical Industries, Ltd. is an Israeli company with its principal place of business at 5 Basel Street, P.O. Box 3190, Petach Tikva, 49131, Israel. Teva Ltd. develops, manufactures, sells and/or distributes generic drugs, including the generic Suboxone® products and generic Subutex® products throughout the United States, including in this District and including through its subsidiaries and agents, Actavis Elizabeth, Actavis Pharma, and Teva USA.

9. Teva USA is a wholly-owned subsidiary of Teva Ltd.

10. Actavis Pharma is a wholly-owned indirect subsidiary of Teva USA and Teva Ltd.

11. Actavis Elizabeth is a wholly-owned indirect subsidiary of Teva USA and Teva Ltd.

JURISDICTION AND VENUE

12. This is an action for patent infringement arising under the Patent Laws of the United States, Title 35, United States Code. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338.

13. This Court has personal jurisdiction over Actavis Elizabeth. Actavis Elizabeth is a Delaware company. It is registered with the Delaware Department of State: Division of Corporations under file number 0875422 and maintains a registered agent for service of process in Delaware.

14. Actavis Elizabeth regularly does or solicits business in Delaware, engages in other persistent courses of conduct in Delaware, and/or derives substantial revenue from services or things used or consumed in Delaware, including the generic Suboxone® products and generic Subutex® products, demonstrating that Actavis Elizabeth has continuous and systematic contacts with Delaware.

15. Actavis Elizabeth is in the business of manufacturing and selling generic pharmaceutical products, including the generic Suboxone® products and generic Subutex® products, that are distributed throughout the United States, including in the state of Delaware.

16. Actavis Elizabeth holds an active Delaware pharmacy wholesale license (No. A4-0000069) and an active Delaware controlled substances distributor/manufacturer license (No. DS0751).

17. Actavis Elizabeth has availed itself of this forum initiating civil actions in this jurisdiction, including but not limited to Actavis Elizabeth LLC v. Novartis Corporation et al., 16-cv-00604-RGA (D. Del 2016).

18. Actavis Elizabeth has purposefully availed itself of the privilege of conducting activities in Delaware and its conduct and connection with Delaware are such that it should reasonably anticipate being haled into court in the state.

19. This Court has personal jurisdiction over Actavis Pharma. Actavis Pharma is a Delaware company. It is registered with the Delaware Department of State: Division of Corporations under file number 2352578 and maintains a registered agent for service of process in Delaware.

20. Actavis Pharma regularly does or solicits business in Delaware, engages in other persistent courses of conduct in Delaware, and/or derives substantial revenue from services

or things used or consumed in Delaware, including the generic Suboxone® products and generic Subutex® products, demonstrating that Actavis Pharma has continuous and systematic contacts with Delaware.

21. Actavis Pharma is in the business of manufacturing and selling generic pharmaceutical products, including the generic Suboxone® products and generic Subutex® products, that are distributed throughout the United States, including in the state of Delaware.

22. Actavis Pharma holds active Delaware pharmacy wholesale licenses (Nos. A4-0000627, A4-0000683 and A4-0002328) and active Delaware controlled substances distributor/manufacturer license (Nos. DS0503 and DS0319).

23. Actavis Pharma has availed itself of this forum by consenting to personal jurisdiction and/or asserting counterclaims in other civil actions initiated in this jurisdiction, including but not limited to *Amgen, Inc. v. Watson Laboratories, Inc. et al.*, 16-cv-00855-GMS (D. Del 2016).

24. Actavis Pharma has purposefully availed itself of the privilege of conducting activities in Delaware and its conduct and connection with Delaware are such that it should reasonably anticipate being haled into court in the state.

25. This Court has personal jurisdiction over Teva USA. Teva USA is a Delaware company. It is registered with the Delaware Department of State: Division of Corporations under file number 2053734 and maintains a registered agent for service of process in Delaware.

26. Teva USA regularly does or solicits business in Delaware, engages in other persistent courses of conduct in Delaware, and/or derives substantial revenue from services or things used or consumed in Delaware, including the generic Suboxone® products and generic

Subutex® products, demonstrating that Teva USA has continuous and systematic contacts with Delaware.

27. Teva USA is in the business of manufacturing and selling generic pharmaceutical products that are distributed throughout the United States, including in the state of Delaware. Teva USA directly or through its affiliates and agents develops, formulates, manufactures, markets, and/or sells pharmaceutical products, including the generic Suboxone® products and generic Subutex® products, throughout the United States and in this judicial district.

28. Teva USA holds active Delaware pharmacy wholesale licenses (Nos. A4-0001468 and A4-0001447) and active Delaware controlled substances distributor/manufacturer license (Nos. DM-0007115 and DM-0006546).

29. Teva USA has availed itself of this forum by initiating civil actions in this jurisdiction, including but not limited to *Teva Pharms. USA, Inc. et al. v. Biocon Ltd. et al.*, 16-cv-278-GMS (D. Del. 2016) and *Teva Pharms. USA, Inc. et al. v. Dr. Reddy's Labs., Ltd. et al.*, 15-cv-306-GMS (D. Del. 2015).

30. Teva USA has purposefully availed itself of the privilege of conducting activities in Delaware and its conduct and connection with Delaware are such that it should reasonably anticipate being haled into court in the state.

31. This Court has personal jurisdiction over Teva Ltd. Teva Ltd. regularly does or solicits business in Delaware, engages in other persistent courses of conduct in Delaware, and/or derives substantial revenue from services or things used or consumed in Delaware, including the generic Suboxone® products and generic Subutex® products, demonstrating that Teva Ltd. has continuous and systematic contacts with Delaware.

32. Teva Ltd. is in the business of manufacturing and selling generic pharmaceutical products that are distributed throughout the United States, including in the state of Delaware. Teva Ltd. directly or through its affiliates and agents develops, formulates, manufactures, markets, and/or sells pharmaceutical products, including the generic Suboxone® products and generic Subutex® products, throughout the United States and in this judicial district.

33. Teva Ltd. has availed itself of this forum by initiating civil actions in this jurisdiction, including but not limited to *Teva Pharms. USA, Inc. et al. v. Biocon Ltd. et al.*, 16-cv-278-GMS (D. Del. 2016) and *Teva Pharms. USA, Inc. et al. v. Dr. Reddy's Labs., Ltd. et al.*, 15-cv-306-GMS (D. Del. 2015).

34. Teva Ltd. has purposefully availed itself of the privilege of conducting activities in Delaware and its conduct and connection with Delaware are such that it should reasonably anticipate being haled into court in the state.

35. Defendants collaborate to manufacture, import, market, distribute, and/or sell pharmaceutical products (including the generic Suboxone® products and generic Subutex® products) throughout the United States, including in the state of Delaware.

36. This Court has personal jurisdiction over Defendants by virtue of, *inter alia*, the above-mentioned facts.

37. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391 and 28 U.S.C. § 1400(b).

OREXO AND THE PATENT-IN-SUIT

38. Orexo develops new medicines by applying innovative drug delivery technologies to drug substances. The '996 patent resulted from Orexo's work in developing innovative methods of treatment with sublingual tablets.

39. The ’996 patent (copy attached as Exhibit A) is entitled “Pharmaceutical Compositions for the Treatment of Acute Disorders” and was duly and legally issued by the United States Patent and Trademark Office (“USPTO”) on June 4, 2013. The ’996 patent claims methods of treatment comprising administration of pharmaceutical compositions containing buprenorphine.

40. The named inventors of the ’996 patent are Anders Pettersson and Christer Nystrom. The ’996 patent is assigned to Orexo AB.

41. Orexo manufactures and sells Zubsolv®, a sublingual tablet for the treatment of opioid addiction that contains the active ingredients buprenorphine and naloxone.

42. The ’996 patent is listed in the FDA’s Orange Book for Zubsolv®.

43. Actavis Elizabeth had knowledge of the ’996 patent at least as early as May 16, 2014, when it sent Orexo a Paragraph IV Notice Letter regarding ANDA No. 206258 for a proposed generic Zubsolv® product that addressed the ’996 patent.

44. Actavis Elizabeth already unsuccessfully challenged the validity of the ’996 patent. On November 15, 2016, the U.S. District Court for the District of Delaware held that the ’996 patent claims were valid. (C.A. No. 14-829(SLR)(SRF)). Defendants did not appeal the Court’s decision.

COUNT I - PATENT INFRINGEMENT (GENERIC SUBOXONE® PRODUCTS)

45. Plaintiffs repeat and reallege paragraphs 1 through 44 as if fully set forth herein.

46. Defendants manufacture, sell, offer for sale, and/or import into the U.S. generic Suboxone® products.

47. Actavis Elizabeth manufactures the generic Suboxone® products for sale throughout the United States, including in Delaware.

48. Actavis Pharma distributes the generic Suboxone® products throughout the United States, including in Delaware.

49. Teva Ltd., through Teva USA, directs Actavis Elizabeth to manufacture and Actavis Pharma to distribute the generic Suboxone® products throughout the United States, including in Delaware. Teva Ltd. and Teva USA acted jointly and collectively to manufacture, sell, offer for sale, and/or import into the U.S. generic Suboxone® products either indirectly through their subsidiaries or affiliates or directly. Actavis Elizabeth and Actavis Pharma are indirect wholly owned subsidiaries of Teva USA and Teva Ltd. and are controlled by and/or act as agents of Teva USA and Teva Ltd.

50. The generic Suboxone® products are sold by Defendants pursuant to ANDA No. 091422.

51. Defendants started marketing, offering for sale, and selling the generic Suboxone® products on or about June 24, 2013.

52. The generic Suboxone® products contain the active ingredients buprenorphine hydrochloride and naloxone hydrochloride dihydrate and are available in 2mg/0.5mg and 8mg/2mg dosage strengths.

53. The generic Suboxone® products contain the inactive ingredients citric acid anhydrous, crospovidone, lactose monohydrate, magnesium stearate, mannitol, N&A lemon FL, pregelatinized starch (maize), povidone, sodium citrate, and sucralose.

54. ’996 patent claim 1 recites:

> A method comprising sublingual administration to an individual of a pharmaceutical composition in the form of a tablet sized for placement under a tongue, wherein the composition comprises
>
> (a) water-soluble carrier particles having exterior surfaces,

> (b) microparticles of buprenorphine or a pharmaceutically-acceptable salt thereof, wherein said microparticles are smaller than the carrier particles and are admixed with the carrier particles, and
>
> (c) particles of a bioadhesion and/or mucoadhesion promoting agent consisting essentially of a polymer that swells when brought into contact with saliva, admixed with the carrier particles,
>
> wherein the microparticles of buprenorphine or a pharmaceutically-acceptable salt thereof are presented at the exterior surfaces of the carrier particles.

55. The generic Suboxone® products as marketed are in the form of a tablet sized for placement under a tongue and are administered sublingually. The label and instructions provided by Defendants with the generic Suboxone® products instruct physicians and patients that the tablets be administered sublingually (i.e., placed under the tongue).

56. The generic Suboxone® products as marketed contain water-soluble carrier particles having exterior surfaces. As non-limiting examples, the generic Suboxone® products contain at least mannitol and lactose.

57. The generic Suboxone® products contain microparticles of buprenorphine hydrochloride that are smaller than particles of mannitol and lactose (carrier particles) and are admixed with them.

58. The generic Suboxone® products as marketed contain particles of a bioadhesion and/or mucoadhesion agent consisting essentially of a polymer that swells when brought into contact with saliva. As a non-limiting example, the generic Suboxone® products contains at least crospovidone, which is a bioadhesion and/or mucoadhesion agent consisting essentially of a polymer that swells when brought into contact with saliva.

59. The particles of crospovidone (bioadhesion and/or mucoadhesion agent) in the generic Suboxone® products as marketed are admixed with mannitol and/or lactose (carrier particles).

60. The generic Suboxone® products contain microparticles of buprenorphine hydrochloride presented at the exterior surfaces of particles of mannitol and/or lactose (carrier particles).

61. ’996 patent claim 2 recites:

> A method comprising sublingual administration of at least one dosage unit of an essentially water free pharmaceutical composition to an individual, said pharmaceutical composition comprising an effective amount of buprenorphine or a pharmaceutically-acceptable salt thereof in the form of microparticles adhered to the surfaces of carrier particles which are substantially larger than said microparticles and are essentially water-soluble, and a bioadhesion and/or mucoadhesion promoting agent.

62. The generic Suboxone® products label and instructions provided by Defendants instruct physicians and patients that the tablets (at least one dosage unit) be administered sublingually.

63. The generic Suboxone® products as marketed are essentially water free tablets.

64. The generic Suboxone® products as marketed contain an effective amount of buprenorphine hydrochloride.

65. The generic Suboxone® products as marketed contain microparticles of buprenorphine hydrochloride that are adhered to surfaces of carrier particles.

66. The generic Suboxone® products as marketed contain particles of mannitol and/or lactose (carrier particles) which are substantially larger than microparticles of buprenorphine hydrochloride and are essentially water-soluble.

67. The generic Suboxone® products as marketed contain at least crospovidone, which is an example of a bioadhesion and/or mucoadhesion agent.

68. The use of the generic Suboxone® products by physicians and patients according to the labeling and instructions provided by Defendants infringes claims 1 and 2 of the '996 patent.

69. Defendants actively induced and continue to induce physicians and patients to infringe claims 1 and 2 of the '996 patent in violation of 35 U.S.C. § 271(b) by instructing physicians and patients to use the generic Suboxone® products in an infringing manner. Defendants' active inducement includes, for example, selling or offering for sale the generic Suboxone® products with instructions in the product label that the products must be administered sublingually. Defendants have done so with knowledge of the '996 patent and that they are instructing patients and physicians to infringe, and have done so with the intent that claims 1 and 2 of the '996 patent be infringed.

70. Defendants contribute to infringement of claims 1 and 2 of the '996 patent in violation of 35 U.S.C. § 271(c) by offering to sell and selling the generic Suboxone® products within the United States tablets for use by physicians and patients. Defendants know the generic Suboxone® products to be especially made or especially adapted for use in infringement of claims 1 and 2 of the '996 patent, and to not be a staple article or commodity of commerce suitable for substantial noninfringing use.

71. Plaintiffs have been damaged as a result of Defendants' infringing conduct and are entitled to recover damages that adequately compensate Plaintiffs for Defendants' infringement, which shall not be less than a reasonable royalty, together with interest and costs as fixed by the Court under 35 U.S.C. § 284.

COUNT II – PATENT INFRINGEMENT (GENERIC SUBUTEX® PRODUCTS)

72. Plaintiffs repeat and reallege paragraphs 1 through 71 as if fully set forth herein.

73. Defendants manufacture, sell, offer for sale, and/or import into the U.S. generic Subutex® products.

74. Actavis Elizabeth manufactures the generic Subutex® products for sale throughout the United States, including in Delaware.

75. Actavis Pharma distributes the generic Subutex® products throughout the United States, including in Delaware.

76. Teva Ltd., through Teva USA, directs Actavis Elizabeth to manufacture and Actavis Pharma to distribute the generic Subutex® products throughout the United States, including in Delaware. Teva Ltd. and Teva USA acted jointly and collectively to manufacture, sell, offer for sale, and/or import into the U.S. generic Subutex® products either indirectly through their subsidiaries or affiliates or directly. Actavis Elizabeth and Actavis Pharma are indirect wholly owned subsidiaries of Teva USA and Teva Ltd. and are controlled by and/or act as agents of Teva USA and Teva Ltd.

77. The generic Subutex® products are sold pursuant to ANDA No. 090819.

78. Defendants started marketing the generic Subutex® products on or about April 10, 2015.

79. The generic Subutex® products contain the active ingredient buprenorphine hydrochloride and are available in 2mg and 8mg dosage strengths.

80. The generic Subutex® products contain the inactive ingredients citric acid anhydrous, crospovidone, FD&C yellow #6 HT aluminum lake, lactose monohydrate, magnesium stearate, mannitol, pregelatinized starch (maize), povidone, sodium citrate dihydrateas.

81. ’996 patent claim 1 recites:

> A method comprising sublingual administration to an individual of a pharmaceutical composition in the form of a tablet sized for placement under a tongue, wherein the composition comprises
>
> (a) water-soluble carrier particles having exterior surfaces,
>
> (b) microparticles of buprenorphine or a pharmaceutically-acceptable salt thereof, wherein said microparticles are smaller than the carrier particles and are admixed with the carrier particles, and
>
> (c) particles of a bioadhesion and/or mucoadhesion promoting agent consisting essentially of a polymer that swells when brought into contact with saliva, admixed with the carrier particles,
>
> wherein the microparticles of buprenorphine or a pharmaceutically-acceptable salt thereof are presented at the exterior surfaces of the carrier particles.

82. The generic Subutex® products as marketed are in the form of a tablet sized for placement under a tongue and are administered sublingually. The label and instructions provided by Defendants with the generic Subutex® products instruct physicians and patients that the tablets be administered sublingually (i.e., placed under the tongue).

83. The generic Subutex® products as marketed contain water-soluble carrier particles having exterior surfaces. As non-limiting examples, the generic Subutex® products contain at least mannitol and lactose.

84. The generic Subutex® products contain microparticles of buprenorphine hydrochloride that are smaller than particles of mannitol and lactose (carrier particles) and are admixed with them.

85. The generic Subutex® products as marketed contain particles of a bioadhesion and/or mucoadhesion agent consisting essentially of a polymer that swells when brought into contact with saliva. As a non-limiting example, the generic Subutex® products contains at least crospovidone, which is a bioadhesion and/or mucoadhesion agent consisting essentially of a polymer that swells when brought into contact with saliva.

86. The particles of crospovidone (bioadhesion and/or mucoadhesion agent) in the generic Subutex® products as marketed are admixed with mannitol and/or lactose (carrier particles).

87. The generic Subutex® products contain microparticles of buprenorphine hydrochloride presented at the exterior surfaces of particles of mannitol and/or lactose (carrier particles).

88. ’996 patent claim 2 recites:

> A method comprising sublingual administration of at least one dosage unit of an essentially water free pharmaceutical composition to an individual, said pharmaceutical composition comprising an effective amount of buprenorphine or a pharmaceutically-acceptable salt thereof in the form of microparticles adhered to the surfaces of carrier particles which are substantially larger than said microparticles and are essentially water-soluble, and a bioadhesion and/or mucoadhesion promoting agent.

89. The generic Subutex® products label and instructions provided by Defendants instruct physicians and patients that the tablets (at least one dosage unit) be administered sublingually.

90. The generic Subutex® products as marketed are essentially water free tablets.

91. The generic Subutex® products as marketed contain an effective amount of buprenorphine hydrochloride.

92. The generic Subutex® products as marketed contain microparticles of buprenorphine hydrochloride that are adhered to surfaces of carrier particles.

93. The generic Subutex® products as marketed contain particles of mannitol and/or lactose (carrier particles) which are substantially larger than microparticles of buprenorphine hydrochloride and are essentially water-soluble.

94. The generic Subutex® products as marketed contain at least crospovidone, which is an example of a bioadhesion and/or mucoadhesion agent.

95. The use of the generic Subutex® products by physicians and patients according to the labeling and instructions provided by Defendants infringes claims 1 and 2 of the ’996 patent.

96. Defendants actively induced and continue to induce physicians and patients to infringe claims 1 and 2 of the ’996 patent in violation of 35 U.S.C. § 271(b) by instructing physicians and patients to use the generic Subutex® products. Defendants’ active inducement includes, for example, selling or offering for sale the generic Subutex® products with instructions in the product label that the products must be administered sublingually. Defendants have done so with knowledge of the ’996 patent and that they are instructing patients and physicians to infringe, and have done so with the intent that claims 1 and 2 of the ’996 patent be infringed.

97. Defendants contribute to infringement of claims 1 and 2 of the ’996 patent in violation of 35 U.S.C. § 271(c) by offering to sell and selling the generic Subutex® products within the United States tablets for use by physicians and patients. Defendants know the generic Subutex® products to be especially made or especially adapted for use in infringement of claims 1 and 2 of the ’996 patent, and to not be a staple article or commodity of commerce suitable for substantial noninfringing use.

98. Plaintiffs have been damaged as a result of Defendants’ infringing conduct and are entitled to recover damages that adequately compensate Plaintiffs for Defendants’ infringement, which shall not be less than a reasonable royalty, together with interest and costs as fixed by the Court under 35 U.S.C. § 284.

WILLFUL INFRINGEMENT

99. Plaintiffs repeat and reallege paragraphs 1 through 98 as if fully set forth herein.

100. Defendants had knowledge of the ’996 patent in advance of the filing of this Complaint.

101. Actavis Elizabeth had knowledge of the ’996 patent at least as early as May 16, 2014, when it sent Orexo a Paragraph IV Notice Letter regarding ANDA No. 206258 for a proposed generic Zubsolv® product that addressed the ’996 patent.

102. On November 15, 2016, the U.S. District Court for the District of Delaware held that the ’996 patent is valid. (C.A. No. 14-829(SLR)(SRF)). Defendants did not appeal that decision.

103. Defendants knew or should have known that their manufacture, offer for sale, and sale of the generic Suboxone® products and generic Subutex® products and their instructions to customers, physicians and patients, infringe claims 1 and 2 of the ’996 patent. Defendants’ infringement is objectively reckless, knowing, deliberate, and willful.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for a judgment in their favor and against Defendants and respectfully request the following relief:

A. A judgment that Defendants infringed the ’996 patent under 35 U.S.C. § 271(b) by manufacturing, selling, offering to sell, and/or importing the generic Suboxone® products with instructions that the products be administered sublingually;

B. A judgment that Defendants infringed the ’996 patent under 35 U.S.C. § 271(b) by manufacturing, selling, offering to sell, and/or importing the generic Subutex® products with instructions that the products be administered sublingually;

C. A judgment that Defendants infringed the ’996 patent under 35 U.S.C. § 271(c) by offering to sell and selling the generic Suboxone® products within the United States knowing the generic Suboxone® products to be especially made or especially adapted for use in infringement of claims 1 and 2 of the ’996 patent, and not to be a staple article or commodity of commerce suitable for substantial noninfringing use;

D. A judgment that Defendants infringed the ’996 patent under 35 U.S.C. § 271(c) by offering to sell and selling the generic Subutex® products within the United States knowing the generic Subutex® products to be especially made or especially adapted for use in infringement of claims 1 and 2 of the ’996 patent, and not to be a staple article or commodity of commerce suitable for substantial noninfringing use;

E. A permanent injunction restraining and enjoining Defendants and their officers, agents, attorneys, and employees, and those acting in privity or concert therewith, from engaging in the commercial manufacture, use, offer for sale, sale, and/or importation of the generic Suboxone® products and generic Subutex® products until the expiration of the ’996 patent or any later date of exclusivity to which Plaintiffs are or become entitled;

F. A judgment that Defendants pay damages adequate to compensate Plaintiffs for Defendants’ infringement of the ’996 patent, but in no event less than a reasonable royalty, together with prejudgment and post-judgment interest thereon;

G. A judgment that Defendants account for post-verdict infringement and pay no less than a reasonable royalty, together with interest thereon;

H. A judgment that Defendants’ infringement is deliberate and willful and that Defendants be ordered to pay treble damages under 35 U.S.C. § 284;

I. A judgment declaring this case "exceptional" under 35 U.S.C. § 285 and an award of Plaintiffs' attorneys' fees, etc.;

J. Costs and expenses in this action; and

K. Such other and further relief as the Court may deem just and proper.

JURY DEMAND

Plaintiffs hereby demand a jury trial as to all issues so triable.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Derek J. Fahnestock

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